

Senate File 2102 - Introduced

SENATE FILE 2102

BY BOLKCOM

A BILL FOR

1 An Act relating to the coverage of direct-acting antiviral
2 drugs for Medicaid beneficiaries living with a chronic
3 hepatitis C virus infection.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. MEDICAID PROGRAM COVERAGE — DIRECT-ACTING
2 ANTIVIRAL DRUGS — HEPATITIS C VIRUS (HCV) INFECTION.

3 1. The department of human services shall adopt rules
4 pursuant to chapter 17A, shall amend all Medicaid managed care
5 contracts, and shall submit any Medicaid state plan amendments
6 to the centers for Medicare and Medicaid services of the United
7 States department of health and human services (CMS) for
8 approval, as necessary, to require that direct-acting antiviral
9 drugs that are approved by the United States food and drug
10 administration (FDA) for the treatment of chronic HCV-infected
11 patients as a medically accepted indication as defined in 42
12 U.S.C. §1396r-8(k)(6), are a covered outpatient drug under
13 the Medicaid program, and shall be covered consistently for
14 Medicaid beneficiaries under both the fee-for-service and
15 managed care methodologies in accordance with the Medicaid
16 state plan. The rules adopted, Medicaid managed care contracts
17 amended, and state plan amendment submitted shall comply with
18 all of the following requirements:

19 a. Coverage for the outpatient drugs shall be provided
20 in accordance with 42 U.S.C. §1396r-8 and with Medicaid drug
21 rebate program notice release No. 172 issued by CMS on November
22 5, 2015.

23 b. Any limitation on coverage of such drugs, including
24 utilization controls such as prior authorization and placement
25 on the preferred drug list, shall not unreasonably restrict
26 access to these drugs for a medically accepted indication as
27 defined in 42 U.S.C. §1396r-8(k)(6), including that provision
28 of the drugs shall not be based on a beneficiary's Metavir
29 fibrosis score or disease severity, shall not require a period
30 of abstinence from drug and alcohol abuse, and shall not
31 require prescribing by a specific provider type.

32 c. Coverage shall be consistent with the guidelines
33 published by the American association for the study of liver
34 diseases (AASLD), the infectious diseases society of America
35 (IDSA), and the international antiviral society-USA (IAS-USA)

1 to the extent consistent with federal law and regulation.

2 d. If utilization controls are provided, such utilization
3 controls shall ensure that appropriate access to the covered
4 drugs is consistent with 42 C.F.R. §438.210 and specifically
5 must ensure that the drugs are provided in a manner that is
6 sufficient in amount, duration, and scope to reasonably achieve
7 the purpose for which the drugs are furnished and are not
8 arbitrarily denied or reduced in amount, duration, or scope
9 solely because of the diagnosis, type of illness, or condition
10 of the beneficiary.

11 2. Additionally, the department of human services shall do
12 all of the following:

13 a. Implement programming to provide patients who are
14 undergoing and who have completed direct-acting antiviral HCV
15 drug treatment with supportive care and surveillance to enhance
16 their adherence to regimens and increase success rates.

17 b. Collaborate with the department of public health,
18 bureau of HIV, STD, and hepatitis to provide surveillance and
19 determine the return on investment, benefits, and outcomes
20 resulting from the provision of treatment to all chronic
21 HCV-infected Medicaid beneficiaries, including due to averting
22 new infections.

23 EXPLANATION

24 The inclusion of this explanation does not constitute agreement with
25 the explanation's substance by the members of the general assembly.

26 This bill relates to coverage of direct-acting antiviral
27 drugs for a chronic hepatitis C virus (HCV) infection under the
28 Medicaid programs.

29 The bill requires the department of human services to adopt
30 rules pursuant to Code chapter 17A, amend all Medicaid managed
31 care contracts, and submit any Medicaid state plan amendments
32 to the centers for Medicare and Medicaid services of the United
33 States department of health and human services (CMS) for
34 approval, as necessary, to require that direct-acting antiviral
35 drugs that are approved by the United States food and drug

1 administration (FDA) for the treatment of chronic HCV-infected
2 patients as a medically accepted indication are a covered
3 outpatient drug under the Medicaid program, and shall be
4 covered consistently for Medicaid beneficiaries under both the
5 fee-for-service and managed care methodologies in accordance
6 with the Medicaid state plan.

7 The bill requires that the rules adopted, and state plan
8 amendment submitted, shall comply with all of the following
9 requirements:

10 1. Coverage for the outpatient drugs shall be provided
11 in accordance with 42 U.S.C. §1396r-8 and with Medicaid drug
12 rebate program notice release No. 172 issued by CMS on November
13 5, 2015.

14 2. Any limitation on coverage of such drugs, including
15 utilization controls such as prior authorization and placement
16 on the preferred drug list, shall not unreasonably restrict
17 access to these drugs for a medically accepted indication,
18 including that provision of the drugs shall not be based on a
19 beneficiary's Metavir fibrosis score or disease severity, shall
20 not require a period of abstinence from drug and alcohol abuse,
21 and shall not require prescribing by a specific provider type.

22 3. Coverage shall be consistent with the guidelines
23 published by the American association for the study of liver
24 diseases (AASLD), the infectious diseases society of America
25 (IDSA), and the international antiviral society-USA (IAS-USA) to
26 the extent consistent with federal law and regulation.

27 4. If utilization controls are provided, such utilization
28 controls shall ensure that appropriate access to the covered
29 drugs is consistent with federal regulations and specifically
30 must ensure that the drugs are provided in a manner that is
31 sufficient in amount, duration, and scope to reasonably achieve
32 the purpose for which the drugs are furnished and are not
33 arbitrarily denied or reduced in amount, duration, or scope
34 solely because of the diagnosis, type of illness, or condition
35 of the beneficiary.

1 The bill also requires DHS to implement programming to
2 provide patients who are undergoing and who have completed
3 direct-acting antiviral HCV drug treatment with supportive care
4 and surveillance to enhance their adherence to regimens and
5 increase success rates, and to collaborate with the department
6 of public health, bureau of HIV, STD, and hepatitis, to provide
7 surveillance and determine the return on investment, benefits,
8 and outcomes resulting from the provision of treatment to all
9 chronic HCV-infected Medicaid beneficiaries, including due to
10 averting new infections.